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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,069	09/11/2003	Ronald L. Hayes	UF-530XT	7655

23557 7590 05/16/2007  
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EXAMINER
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WEGERT, SANDRA L

ART UNIT	PAPER NUMBER
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1647

MAIL DATE	DELIVERY MODE
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05/16/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/660,069	HAYES ET AL.
	Examiner Sandra Wegert	Art Unit 1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 20 February 2007.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-49 is/are pending in the application.  
 4a) Of the above claim(s) 1-20 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 21-49 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 11 September 2003 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date 4.27/04, 11/24/06, 12/22/06

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

***Status of Application, Amendments, and/or Claims***

Applicants amendments and Response, submitted 20 February 2007 has been entered.

Claims 1-19 remain withdrawn. Claims 21-25, 28, 29-34, 36, and 37 are amended. Claims 38-49 are new.

Claims 21-49 are under examination in the instant application.

**Withdrawn Objections and/or Rejections**

**Informalities**

***Title***

The objection to the disclosure for having a nondescript title is *withdrawn*. Applicants amended the title to more clearly reflect the invention (20 February 2007).

***Continuity***

The objection to the continuity information in the first paragraph of the Specification is *withdrawn*. The provisional application listed as the prior application had the wrong filing date, according to the Oath. Applicants amended the specification to correct the filing date of the provisional application (20 February 2007).

***Claim Objections***

The objection to claims 22 and 31 because they did not end in a period is *withdrawn*.

Applicants amended both claims to insert a period (20 February 2007).

The objection to claims 25 and 34, for depending from rejected base claims, is *withdrawn*. New rejections for Claims 25 and 34 are below.

***Claim Rejections- 35 USC § 112, first paragraph – Written Description.***

The rejection of Claims 21-24, 26-33 and 35-37 under 35 U.S.C. 112, first paragraph, for lack of Written Description is *withdrawn*. The claims had previously recited an "agent" that binds spectrin breakdown products, which could include ligands other than antibodies. Applicants amended Claims 21-24, 26-33 and 35-37 to remove references to agents other than the specific antibodies used (20 February 2007).

***-35 USC § 112, second paragraph***

The rejection of claims 23 and 32 for reciting an agent that "does not" bind one of the SBDP's is *withdrawn*. Applicants amended the claims to recite that the agent (now an antibody) *does* bind an SBDP (20 February 2007).

**Maintained/New Objections and/or Rejections**

***Claim rejections- 35 USC §103, obviousness***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections

set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of Claims 21-37 under 35 U.S.C. 103(a) for being unpatentable over Lynch, et al (US Patent, 5,118, 606, of record) is *maintained*. Lynch, et al, teach the methods recited in instant claims 1-20. They also recite using the methods to detect spectrin breakdown products. They recite methods for detecting spectrin breakdown products in tissues in contact with the nervous system and recite the involvement of calpain. They also recite several methods of detecting spectrin breakdown products on immobilized substrates. They do not teach the specific spectrin breakdown products, as recited in Claims 21-37 of the instant Application.

The applicants' interpretation of the Lynch, et al Patent is correct (2 February 2007). That group made a polyclonal antibody to  $\alpha$ -spectrin that could detect BDP1 and BDP2, which are two SBDP's produced by calpain. In other words, the antibody made to the full-length spectrin could coincidentally detect two SBDP's, although not specifically and independently. In fact, the patent's authors seem not to be aware of the other calpain breakdown products nor of the products produced by caspase.

However, the amended claims are still obvious over the '606 patent. This is because the amended independent claims still recite antibodies that bind to only *one* marker from the list of markers, and that list includes  $\alpha$ -spectrin (same as the '606 patent) and what are presumably BDP1 and BDP2 (also in the Lynch patent). The additions of the words "specifically" and "independently" do not help to distinguish the claims from the prior art if  $\alpha$ -spectrin, for example, is still included as a singular marker in the claims.

Amending claim 21 to recite, for example "at least two markers" would distinguish the claims from the prior art, provided those two markers do not include only spectrin and BDP1 or BDP2. Claim 31, for example, could be amended to read, "binds to markers" to distinguish the claim from the prior art.

***Claim rejections- 35 U.S.C. 101***

35 U.S.C. 101 reads as follows:

**Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.**

Claims 21-29 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims now recite a biological sample and antibodies that bind the several spectrin breakdown products and spectrin. The claims thus read ambiguously on a fluid sample taken from a subject in which may be found both spectrin breakdown products and the subject's own antibodies against those breakdown products. Amending the claims to recite manipulation by the "hand of man" would be remedial. For example, amending independent claims to recite the addition of exogenous antibodies would be remedial.

**Conclusion:** Claims 21-49 are rejected for the reasons recited above.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1647

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

#### **Advisory information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Nickol, can be reached at (571) 272-0835.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

SLW

9 May 2007



EILEEN B. O'HARA  
PRIMA EXAMINER